



DEC 21 2000

K003681

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SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning this Device Modification to Bio-logic Sleepscan for the addition of the Netlink data acquisition module to the product line is summarized below.

Because this is not a CLASS III device, the special certification defined for this section is not required.

PREPARED BY: Bio-logic Systems Corp
One Bio-logic Plaza
Mundelein, IL 60060

TELEPHONE: (847)-949-5200

CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: November 22, 2000

NAME OF DEVICE: Bio-logic Sleepscan Netlink.

COMMON NAME: Digital EEG Recorder, with specific application for Sleep studies..

CLASSIFICATION NAME: Electroencephalograph (per CFR 882.1400).

PREDICATE DEVICE: Bio-logic Sleepscan modification as described in 510(k) #K983913, and Ceegraph Netlink Digital EEG System, 510(k) #K002570.

DESCRIPTION OF THE DEVICE:

The Sleepscan Netlink system patient connection module (headbox) is nearly identical to the secondary Predicate Device, Ceegraph Netlink. It consists of a molded plastic enclosure approximately 10" x 7" x 2.25" in size and weighing approximately 36 oz. It can be configured to perform up to 40 channel data recordings, having 32 AC channels and 8 DC channels. It also contains a small oximeter OEM module manufactured by Nonin, which has previously received FDA clearance for this intended use. Power to the box is supplied with an external medical-grade power supply, which supplies regulated 5 volts DC to a connector at the rear of the box. Communication to the host computer is performed through a standard Ethernet interface connector capable of running at data rates up to 10 MHz (10 base-T). There are 32 touch-proof "safety jack" electrode connections on the top surface of the headbox, along with reference and ground touch-proof jacks. Also, there are 8 additional 3.5 mm jacks for DC interfaces to external transducers on the side of the box. Other connectors (Ethernet, oximeter, body position input, etc.) are located on the rear of the box. Also, there is a 50-pin connector to allow use of smaller auxiliary patient connection modules that can be placed directly on the patient.

The Sleepscan Netlink system consists of a microprocessor board, a digital interface board, a 32-channel analog board, the oximeter board and 8-channel DC interface circuitry on the digital board. The digital interface, analog board and 8-channel DC circuits are the same as those used in the patient connection module (headbox) of the Ceegraph Netlink secondary Predicate Device. These boards provide patient isolation and signal amplification. The 50-pin auxiliary connector is the same as the auxiliary connector of the Sleepscan Predicate Device. This allows the use of existing patient connection hardware, such as electrode arrays, the 32-channel" electrode connection panel called the "quick disconnect box", and the "Quick-Tilt" headbox, which can be comfortably worn by a patient for long periods of time. The microprocessor board contains program and data memory and control functions for reading the analog data, converting it to digital, and communicating it to the host computer through the Ethernet cable. The digital interface board contains the interface to the A/D converters, DC channel hardware, and the communications hardware. Additional features of the Netlink headbox include an array of LED's to facilitate electrode impedance measurements, an electrode continuity tester, programmable sampling rates, and dedicated pushbuttons to activate collection and impedance measurement.

INTENDED USE:

The Bio-logic Sleepscan product family is indicated for use in the recording and analysis of human physiological data necessary for the diagnosis of Sleep-related disorders. It is intended to record and present this data in a form that can improve the speed of diagnosis and assist in potential treatment decisions. The Sleepscan II – Netlink Data Recording System has a similar intended use to that of the currently-marketed Sleepscan recording systems.

Sleepscan Analysis performs calculations and presents recorded data in various ways on the computer screen and in reports. The Analysis features in the Sleepscan product are intended to be performed without patient hookup being necessary, and may even be performed on a different computer system from that which was used for the patient recording.

The Sleepscan II – Netlink product can be used for patients of all ages, from children to adults, including geriatric patients.

The use of the Sleepscan family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

The primary feature modification represented in this Special 510(k) is for the use of the new Netlink data recording hardware.

PATIENT POPULATION: Adults, children and infants.

SAFETY AND EFFECTIVENESS SUMMARY

To establish the safety and effectiveness of Sleepscan Netlink, this modification to Bio-logic Sleepscan was designed and incorporated into the product line in accordance with the Bio-logic internal Product Development procedures which are intended to meet ISO-9001 and FDA QSR Design Control specifications. A detailed Hazard/Risk analysis for the Ceegraph/Sleepscan Netlink product was performed using the Fault Tree analysis (FTA) approach, and a detailed Risk Assessment was written in accordance with EN-1441, the International Standard for Hazard/Risk analysis.

The Sleepscan Netlink patient-connection hardware utilizes many of the same design principles and circuit designs as are used in the Bio-logic Predicate Devices listed earlier in this document. There are no newly-introduced hardware-related methods by which the patient can be harmed or injured through the use of this device. The same patient isolation methods are used in all products. The Sleepscan Netlink utilizes a medical-grade power supply, as does the Ceegraph Netlink Predicate Device. The 32-channel Sleepscan Predicate Device hardware is powered from the host computer, which is always used with an approved isolation transformer. Direct hardware control of all Netlink functions is provided from the embedded microprocessor and its program code located inside the Netlink package, instead of directly from the host computer program. By distributing the hardware-specific functions to the Netlink headbox, the Windows-based Sleepscan II host computer program has fewer real-time demands, and performance and reliability are improved.

The Sleepscan II Netlink software does not make any final decisions that result in any automatic forms of diagnosis or treatment. All program “recommendations” are subject to review by the Sleep Technologist or Physician, and may be modified, overridden or deleted as determined by a qualified user. The program provides additional functionality to allow the qualified user to review all raw data collected and to perform other data analysis to suit his or her requirements.

The chart on the next page provides a summary comparison of the technological characteristics of the new modified device relative to the predicate devices. This is to demonstrate that this new Sleepscan Netlink device has no significant differences which would adversely affect product safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Mr. Norman E. Brunner
Vice President of Research and Development
Bio-Logic Systems Corporation
One Bio-Logic Plaza
Mundelein, Illinois 60060

Re: K003681
Trade Name: Bio-Logic Sleepscan Netlink
Regulatory Class: II
Product Code: GWQ
Dated: November 28, 2000
Received: November 30, 2000

Dear Mr. Brunner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Norman E. Brunner

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Page 1 of 1

510(k) Number (if known):

Not Assigned

K 003681

Device Name: Sleepscan II – Netlink, a Modification to Bio-logic Sleepscan product.

Indications For Use:

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Sleepscan Analysis performs calculations and presents recorded data in various ways on the computer screen and in reports. The Analysis features in the Sleepscan product are intended to be performed without patient hookup being necessary, and may even be performed on a different computer system from that which was used for the patient recording.

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The use of the Sleepscan family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

mm for cmw
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number 003681

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)